Public Summary

Summary for ARTG Entry:	194485	Ling Zhi Huang Qi Gu Ben Fang a.k.a. Resistance 1 Formula
ARTG entry for	Medicine Listed	
Sponsor	Sun Herbal Pty Ltd	
Postal Address	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	11/02/2012	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Ling Zhi Huang Qi Gu Ben Fang a.k.a. Resistance 1 Formula

Product Type	Single Medicine Product	**Effective Date**	9/04/2018

Permitted Indications

Traditionally used in Chinese medicine to stabilise Exterior

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify lungs/lung-qi

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish spleen-qi

Traditionally used in Chinese medicine to enrich/nourish/tonify/fortify/strengthen kidneys

Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating

Traditionally used in Chinese medicine to calm/soothe/nourish the liver

Indication Requirements

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to disease in any body organ.

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Astragalus membranaceus root Extract dry concentrate	**63.84 mg**
Equivalent: Astragalus membranaceus (Dry)	383.04 mg
Atractylodes macrocephala rhizome Extract dry concentrate	**31.92 mg**
Equivalent: Atractylodes macrocephala (Dry)	191.52 mg
Cuscuta hygrophilae seed Extract dry concentrate	**31.92 mg**
Equivalent: Cuscuta hygrophilae (Dry)	191.52 mg
Dioscorea oppositifolia root Extract dry concentrate	**31.92 mg**
Equivalent: Dioscorea oppositifolia (Dry)	191.52 mg
Ganoderma lucidum mushroom Extract dry concentrate	**31.92 mg**
Equivalent: Ganoderma lucidum (Dry)	191.52 mg
Glycyrrhiza uralensis root Extract dry concentrate	**15.93 mg**
Equivalent: Glycyrrhiza uralensis (Dry)	95.58 mg
Ledebouriella seseloides root Extract dry concentrate	**28.71 mg**
Equivalent: Ledebouriella seseloides (Dry)	172.26 mg
Lycium chinense fruit Extract dry concentrate	**31.92 mg**
Equivalent: Lycium chinense (Dry)	191.52 mg
Ziziphus jujuba fruit Extract dry concentrate	**31.92 mg**
Equivalent: Ziziphus jujuba (Dry)	191.52 mg

Other Ingredients (Excipients)

Agar
carrageenan
hypromellose
sodium citrate dihydrate
soluble maize starch

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